

REMARKS

I. Status of the Claims

Claims 1-5, 7 and 9-16 are pending in the application, and claims 5, 7 and 9 stand withdrawn. Thus, claims 1-4 and 10-16 are under consideration and stand rejected, variously, under 35 U.S.C. §101, §112, first and second paragraphs, and §102. Claims 5-9 are canceled without prejudice or disclaimer to their pursuit in one or more continuing applications. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §101

Claim 10 is rejected as claiming non-statutory subject matter. The claim is canceled, rendering the rejection moot. Reconsideration and withdrawal of the rejection is therefore requested.

III. Rejections Under 35 U.S.C. §112

A. First Paragraph

Claims 1-4 and 11-16 are rejected as allegedly lacking an adequate written description. The grounds for the rejection is that applicants have failed to make publicly available or deposit cell lines producing antibodies designated 4B9 and 4B8. Applicants traverse.

The claims do not recite either antibodies 4B9 or 4B8, nor do they recite cell lines producing such antibodies. The examiner is arguing, essentially, that anything disclosed in applicants' specification must be described in the same fashion as subject matter which is claimed. This is incorrect.

In sum, since applicants are not specifically claiming the antibodies that the examiner argues are not described, applicants need not deposit or otherwise make such antibodies publicly available. Reconsideration and withdrawal of the rejection is therefore requested.

B. Second Paragraph

The claims are rejected for a variety of reasons under §112, second paragraph as allegedly rendering the claims unclear. While in no way acquiescing to the rejections, amendments have been provided that are believed to address the examiner's concerns. Reconsideration and withdrawal of the rejections is therefore requested.

IV. Rejections Under 35 U.S.C. §102

A. Alvarez *et al.* (1999)

Claims 1, 2, 4 and 10-16 are rejected under §102(b) as anticipated by Alvarez *et al.* Applicants traverse on the grounds that the antibodies disclosed in the reference do not selectively recognize fetal blood cells because they bind to an antigen also found on adult erythroid cells, thereby not meeting the limitations of the present claims. However, in the interest of advancing the prosecution, claim 1 has been amended to recite the limitation of claim 3, which is not presently rejected. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Bianchi *et al.* (1993)

Claim 10 is rejected under §102(b) as anticipated by Bianchi *et al.* Applicants traverse on the grounds that the antibodies disclosed in the reference do not selectively recognize fetal blood

cells because they bind to an antigen also found on adult erythroid cells, thereby not meeting the limitations of the present claims. However, in the interest of advancing the prosecution, claim 10 has been canceled. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

C. Tuma *et al.* (2003)

Claims 1-4 and 10-16 are rejected under §102(b) as anticipated by Tuma *et al.* Applicants traverse on the grounds that the antibodies disclosed in the reference do not selectively recognize fetal blood cells because they bind to an antigen also found on adult erythroid cells, thereby not meeting the limitations of the present claims.

First and foremost, Tuma cannot anticipate the claims as it does not actually disclose a monoclonal antibody to I (or i) antigen. Rather, it mentions both polyclonal and monoclonal antibodies without any synthetic or preparatory information, much less a specific antibody or hybridoma designation. Thus, even if there were a credible disclosure in the reference of a monoclonal antibody, the reference would be considered non-enabling for that material. “A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to *enable* a person of ordinary skill in the art to carry out the claimed invention.” MPEP §2121 (emphasis added), citing *Impax Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006).

Indeed, as discussed in the attached declaration from one of the inventors, the antibodies described by Tuma *et al.* as reacting against fetal cells with specificity against the i-epitope lacto-N-hexaasylceramide were derived from auto-antibody of a leukemia patient whose serum reacted not only with the patient’s leukemia cells, but also with fetal cells. No actual monoclonal

antibody or polyclonal serum was ever produced against i-epitope lacto-N-hexaosylceramide. In contrast, the presently claimed antibodies do not react with the I antigen or i-epitope lacto-N-hexaosylceramide. The leukemia cell line K-562 was not recognized by the presently claimed antibodies.

Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to the effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: June 30, 2010